



DOCKET NO.: C1039.70042US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No.: 09/630,319
Confirmation No.: 5464
Filed: July 31, 2000
For: METHODS FOR TREATING AND PREVENTING
INFECTIOUS DISEASE

Examiner: Jane J. Zara
Art Unit: 1635

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 18 day of August, 2004.

Helen C. Lockhart, Ph.D., Reg. No. 39,248

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
C1037.70013US01	10/831,778	April 23, 2004	Bratzler et al.
C1037.70039US01	10/816,220	April 1, 2004	McCluskie et al.
C1039.70022US00	09/337,893	June 21, 1999	Krieg
C1039.70035US01	10/884,866	July 2, 2004	Krieg et al.
¹ C1039.70035US02	10/888,803	July 9, 2004	Krieg et al.
C1039.70048US01	10/769,282	January 30, 2004	Krieg et al.
² C1039.70048US02	10/817,165	April 2, 2004	Krieg et al.
² C1039.70048US03	10/831,647	April 23, 2004	Krieg et al.
² C1039.70048US04	10/847,642	May 15, 2004	Krieg et al.
² C1039.70048US05	10/877,407	June 24, 2004	Krieg et al.
² C1039.70048US06	10/884,852	July 2, 2004	Krieg et al.
² C1039.70048US07	10/888,785	July 9, 2004	Krieg et al.
² C1039.70048US08	10/888,449	July 9, 2004	Krieg et al.
² C1039.70048US09	Not Yet Assigned	July 16, 2004	Krieg et al.
² C1039.70048US10	Not Yet Assigned	July 16, 2004	Krieg et al.
C1039.70057US01	10/838,659	May 3, 2004	Davis et al.
C1039.70058US01	10/831,775	April 23, 2004	Davis et al.
² C1039.70074US00	10/679,710	October 3, 2003	Krieg et al.
C1039.70083US01	10/769,626	January 30, 2004	Krieg et al.
³ C1039.70083US02	10/787,737	February 26, 2004	Krieg et al.
³ C1039.70083US03	10/788,199	February 26, 2004	Krieg et al.
³ C1039.70083US04	10/788,191	February 26, 2004	Krieg et al.

¹Copy not enclosed; see C1039.70035US01, Serial No. 10/884,866 for identical specification

²Copy not enclosed; see C1039.70048US01, Serial No. 10/769,282 for identical specification

³Copy not enclosed; see C1039.70083US01, Serial No. 10/769,626 for identical specification

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
³ C1039.70083US05	10/789,536	February 26, 2004	Krieg et al.
³ C1039.70083US06	10/789,051	February 26, 2004	Krieg et al.
³ C1039.70083US07	10/789,353	February 26, 2004	Krieg et al.
³ C1039.70083US08	10/847,650	May 15, 2004	Krieg et al.
³ C1039.70083US09	10/888,885	July 9, 2004	Krieg et al.
³ C1039.70083US10	10/888,089	July 9, 2004	Krieg et al.
C1040.70006US00	09/316,199	May 21, 1999	McCluskie et al.
⁴ C1040.70006US01	10/888,886	July 9, 2004	McCluskie et al.
C1040.70012US00	10/644,267	August 20, 2003	Davis et al.
C1041.70002US00	09/241,653	February 2, 1999	Wagner et al.
⁵ C1041.70002US01	10/877,369	June 25, 2004	Wagner et al.
⁵ C1041.70002US02	10/876,965	June 25, 2004	Wagner et al.
⁵ C1041.70002US03	10/876,892	June 25, 2004	Wagner et al.
C1041.70005US00	09/355,254	February 22, 2000	Wagner et al.
⁶ C1041.70005US01	10/811,226	March 26, 2004	Wagner et al.
⁶ C1041.70005US02	Not Yet Assigned	July 16, 2004	Wagner et al.
C1041.70016US01	10/884,372	July 2, 2004	Bauer et al.
C1041.70024WO00	PCT/US04/12788	April 22, 2004	Vollmer et al.
C1041.70036US01	10/872,196	June 18, 2004	Lipford et al.
C1041.70040US00	10/666,844	September 19, 2003	Lipford et al.

³Copy not enclosed; see C1039.70083US01, Serial No. 10/769,626 for identical specification

⁴Copy not enclosed; see C1040.70006US00, Serial No. 09/316,199 for identical specification

⁵Copy not enclosed; see C1041.70002US00, Serial No. 09/241,653 for identical specification

⁶Copy not enclosed; see C1041.70005US00, Serial No. 09/355,254 for identical specification

The following are remarks concerning the other information cited:

Comments Regarding Pending Interference No 105,171

Applicants of the above-identified patent application are also named inventors on an issued patent US Patent No. 6,207,646 B1 which is currently involved in an Interference (Interference No. 105,171). The above-identified patent application derives priority from US 6,207,646 B1. In view of the priority Applicants have included on the attached 1449 a listing of all of the motions filed in the Interference to date. Copies are enclosed for the Examiner's

review. If the examiner would like any additional information on this subject she is encouraged to contact Applicants' representative at the number listed below.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

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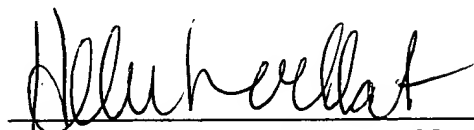
- 5 -

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An early and favorable action is hereby requested.

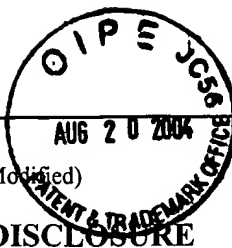
Respectfully submitted,
Krieg et al., Applicant

By:



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Docket No.: C1039.70042US00
Date: August 18, 2004
xNDDx



FORM PTO-1449/A and B (Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 09/630,319 ATTY. DOCKET NO.: C1039.70042US00

FILING DATE: July 31, 2000 CONFIRMATION NO.: 5464

APPLICANT: Krieg et al.

GROUP ART UNIT: 1635 EXAMINER: Jane J. Zara

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U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	5,856,462		Agrawal	01-05-1999
	A2	5,928,636		Alber et al.	07-27-1999
	A3	5,968,909		Agrawal et al.	10-19-1999
	A4	2002/0086295	A1	Raz et al.	07-04-2002
	A5	2004/0006034	A1	Raz et al.	01-08-2004
	A6	2004/0087534	A1	Krieg et al.	05-06-2004
	A7	2004/0132685	A1	Krieg et al.	07-08-2004

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B1	WO	97/28259	A1	The Regents of the University of California		
	B2	WO	98/49288				
	B3	WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
	B4	WO	2004/007743	A2	Coley Pharmaceutical GMBH	01-22-2004	
	B5	WO	2004/039829	A2	Coley Pharmaceutical Group, Ltd.	05-13-2004	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AGARAWL et al., "Pharmacokinetics, biodistribution, and stability of oligonucleotide phosphorothioates in mice", <i>Proc. Natl. Acad. Sci. USA</i> Vol 88, pp. 7595-7599, September 1991	
	C2	CHELVARAJAN., "CpG oligodeoxynucleotides overcome the unresponsiveness of neonatal B cells to stimulation with the thymus-independent stimuli anti-IgM and TNP-Ficoll", <i>Eur. J. Immunol.</i> 1999. 29:2808-2818	
	C3	FRANCOIS et al., "Examination of the Inhibitory and Stimulatory Effects of IFN- α , - β , and - γ on Human B-Cell Proliferation Induced by Various B-Cell Mitogens", <i>Clinical Immunology and Immunopathology</i> , 48, 297-306 (1988).	
	C4	JOHNSON et al., <i>Immunopharmacology, Infection, and Disease</i> , 291-301, 1987.	
	C5	KATAOKA et al., "Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from <i>Mycobacterium bovis</i> BCG complexed with poly-L-lysine and carboxymethylcellulose", <i>Japan Journal of Medical Science and Biology</i> , 43(5):171-82, 1990.	
	C6	KLINMAN et al., "Contribution of CpG motifs to the immunogenicity of DNA vaccines", <i>Journal of Immunology</i> , 158(8): 3635-9, 1997.	
	C7	KRIEG et al., Abstract from 1996 meeting on Molecular Approaches to the Control of Infectious Diseases, Cold Spring Harbor Laboratory, September 9-13, 1996. p.116.	
	C8	KUBY "Cytokines" <i>Immunology</i> 13:pg 297-322:1994	
	C9	KURAMOTO et al., "Changes of host cell infiltration into Meth A fibrosarcoma tumor during the course of regression induced by injections of a BCG nucleic acid fraction", <i>International Immunopharmacology</i> , 14(5): 773-782, 1992.	
	C10	KURAMOTO et al., <i>Microbe. Immunol.</i> 33 (11) 929-940, 1989	
	C11	LIPFORD et al., "CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants", <i>European Journal of Immunology</i> , 27(9): 2340-4, 1997.	



INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/630,319	ATTY. DOCKET NO.: C1039.70042US00
				FILING DATE: July 31, 2000	CONFIRMATION NO.: 5464
				APPLICANT: Krieg et al.	
				GROUP ART UNIT: 1635	EXAMINER: Jane J. Zara
Sheet	2	of	3		

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C12	LIPFORD et al., "Bacterial DNA as immune cell activator", <i>Trends Microbiological</i> , 6(12): 496-500, 1998.	
	C13	PISETSKY et al., "The influence of base sequence on the immunostimulatory properties of DNA", <i>Immunity Research</i> , 19: 35-46, 1999.	
	C14	PISETSKY et al., "The influence of base sequence on the immunological properties of defined oligonucleotides", <i>Immunopharmacology</i> , 40: 199-208, 1998.	
	C15	RAZ et al., "Intradermal gene immunization: The possible role of DNA uptake in the induction of cellular immunity to viruses" <i>Proc. Natl. Acad. Sci. USA</i> Vol. 91, pp. 9519-9253, Sept. 1994	
	C16	UHLMANN, "Recent advances in the medicinal chemistry of antisense oligonucleotides" <i>Current Opinion in Drug Discovery & Development</i> 2000 3(2)	
	C17	VLASSOV et al., "Oligonucleotides in Cells and in Organisms: Pharmacological Considerations"	
	C18	VOLLMER et al., "Characterization of three CpG oligodeoxynucleotide classes with distinct immunostimulatory activities" <i>Eur. J. Immunol.</i> 2004. 34: 251-262	
	C19	WAAG et al., "Injection of inactivated phase I Coxiella burnetii increases non-specific resistance to infection and stimulates lymphokine production in mice", <i>Annual New York Academy of Science</i> , 590: 203-214, 1990.	
	C20	WAGNER, "Bacterial CpG DNA Activates Immune Cells to Signal Infectious Danger" <i>Advances in Immunology</i> Vol 73 329- 1999	
	C21	YI et al., "CpG DNA Rescue of Murine B Lymphoma Cells from Anti-IgM-Induced Growth Arrest and Programmed Cell Death Is Associated with Increased Expression of c-myc and bcl-x _L " <i>The Journal of Immunology</i> , 1996, 157:4918-4925	
	C22	ZHAO et al., "Immunostimulatory Activity of CpG Containing Phosphorothioate Oligodeoxynucleotide is Modulated by Modification of a Single Deoxynucleoside" <i>Bioorganic & Medicinal Chemistry Letters</i> 10 (2000) 1051-1054	
	C23	ZHAO et al., "SITE OF CHEMICAL MODIFICATIONS IN CPG CONTAINING PHOSPHOROTHIOATE OLIGODEOXYNUCLEOTIDE MODULATES ITS IMMUNOSTIMULATORY ACTIVITY" <i>Bioorganic & Medicinal Chemistry Letters</i> 9 (1999) 3453-3458	
	C24	Iowa Miscellaneous Motion 1 Patent Interference No. 105,171	
	C25	Iowa Miscellaneous Motion 2 Patent Interference No. 105,171	
	C26	Iowa Preliminary Motion 3 Patent Interference No. 105,171	
	C27	Iowa Preliminary Motion 4 Patent Interference No. 105,171	
	C28	Iowa Preliminary Motion 5 Patent Interference No. 105,171	
	C29	Iowa Preliminary Motion 6 Patent Interference No. 105,171	
	C30	Iowa Preliminary Motion 7 Patent Interference No. 105,171	
	C31	Iowa Preliminary Motion 8 Patent Interference No. 105,171	
	C32	Iowa Preliminary Motion 9 Patent Interference No. 105,171	
	C33	Iowa Preliminary Motion 10 Patent Interference No. 105,171	
	C34	Regents of The University of California Preliminary Statement	
	C35	Regents of The University of California Preliminary Statement Patent Interference No. 105,171	
	C36	Regents of The University of California Preliminary Motion 1 Patent Interference No. 105,171	
	C37	Regents of The University of California Preliminary Motion 2 Patent Interference No. 105,171	
	C38	Regents of The University of California Preliminary Motion 3 Patent Interference No. 105,171	
	C39	Regents of The University of California Preliminary Motion 4 Patent Interference No. 105,171	
	C40	Regents of The University of California Preliminary Motion 5 Patent Interference No. 105,171	



FORM 149/A and B (Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 3

APPLICATION NO.: 09/630,319

ATTY. DOCKET NO.: C1039.70042US00

FILING DATE: July 31, 2000

CONFIRMATION NO.: 5464

APPLICANT: Krieg et al.

GROUP ART UNIT: 1635

EXAMINER: Jane J. Zara

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C41	Regents of The University of California Preliminary Motion 6 Patent Interference No. 105,171	
	C42	Regents of The University of California Preliminary Motion 7 Patent Interference No. 105,171	
	C43	Regents of The University of California Preliminary Motion 8 Patent Interference No. 105,171	

EXAMINE R

DATE CONSIDERED

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]